



## Monday Morning Practice Pearls #39

### What does it mean to take a patient/participant off-study?

A patient is taken off study when they meet one of the criteria outlined in the off-study section of a protocol. Some examples include but are not limited to:

- Completed study follow-up period
- Participant requests to be withdrawn from study
- Death

### What are the responsibilities of the research nurse related to removing a patient/participant from a protocol?

- Ensure that there is a note in CRIS documenting the date and reason the patient was taken off-study. Ideally this note should be written by an MD, DO, NP or PA. If the research nurse writes the note, then the note should refer to the provider who made the decision to take the patient off-study and the date and reason the patient was taken off-study.
- All participants who meet the off-study criteria must be taken off study in [PRES](#).

**REMEMBER:** Once a patient is taken off study, no further data can be collected.

***NOTE: This applies to all non-screening protocols.***